

REMARKS

Claims 1-16 have been examined in the subject application. Claims 2, 3, 5, 6 and 12 have been rejected under §112 (second paragraph) as being indefinite. Claims 1, 3, 4, 7-10 and 14-16 have been rejected under §102(b) as being anticipated by Ebey (U.S.P. 5,322,655). Claims 5 and 6 have been rejected under §103(a) as being obvious over Ebey in view of Henzpeter (U.S.P. 4,062,914). Claim 2 has been rejected under §103(a) as being obvious over Ebey in view of (Shimada et al. (U.S.P. 3,910,737). Claim 11 has been rejected under §103(a) as being obvious over Ebey in view of Lewis (U.S.P. 4,817,006). Claims 12 and 13 have been rejected under §103(a) as being obvious over Ebey in view of Furtwaengler et al. (U.S.P. 3,507,388).

To overcome the indefiniteness rejections against claims 2-3, 5-6 and 12, the term "powder quantity" etc. has been changed to "quantity of material".

With respect to the §102 rejection based on Ebey (US Patent No. 5,322,655), Applicants believe that the following explanation of the principle underlying the invention may assist the Examiner in the further examination of this application.

Initially, it is noted that monitoring and controlling one tablet parameter, namely the weight, is well-known in the prior art, for instance in Ebey.

As it is generally not feasible or desirable to weigh the quantity of material before supplying it to a die, a parameter, i.e. a process variable, representative of the weight of the quantity of material is measured during compression. The measured value of the parameter is an indirect measure of the tablet weight to be computed on the basis of the relationship between the measured value and the tablet weight. The measurement of the value of the parameter may be carried out by using either of two concepts:

1) The quantity of material is compressed to a predefined and constant thickness, and the parameter measured is the force required to compress the quantity of the material in the die. When using compression to constant thickness, weight variation induces compression force variation.

2) The quantity of material is compressed by means of a constant force, and the parameter measured is the displacement of the punch (corresponding to the thickness of the layer). When using compression at a constant compression force, weight variation induces tablet thickness variation.

The measured value is compared to a set value or target value and, if necessary, regulation of the quantity of material is carried out.

In Ebey, both of the above concepts are mentioned, cf. col. 5, lines 26-31 (concept 1) and col. 5, lines 32-39 (concept 2). However, Ebey only mentions weight control, in both of the compression stations.

Only under ideal circumstances, in which the compacting properties (properties influencing the compression force needed to attain a particular tablet strength or hardness) of the material remain constant, would weight control automatically lead to hardness control using any of the above concepts.

However, the compacting properties actually do change during production due to for instance changes in powder properties (like mean particle size, particle size distribution, humidity, chemical constituents concentration) and heating-up of the tablet press itself. As a consequence, two tablets resulting from the same production line may have different hardness properties, although the weight has been measured and regulated using any of the above concepts.

With respect to the Examiner's interpretation of claim 1, Applicants respectfully do not agree that Ebey discloses hardness control during compression, namely allegedly during compression of the second layer. It is correct that weight measurement is carried out in the first station (first layer) of Ebey. However, during compression at the second station, only weight measurement is carried out. Thus, the fact that the second strain gauge transducer generates a control signal to monitor layer compression force only indicates that a further weight measurement is carried out. This is described in detail in the paragraph following the one referred to by the Examiner, viz. in col. 5, lines 32-39 ("compression information...target force that corresponds to the target weight").

There is thus no mention of measuring a parameter representative of the hardness in either of the two stations. Furthermore, there is no mention of regulating the degree of compression that the quantity of material is subjected to during main-compression. Ebey only discloses regulation of the quantity of material, cf. for instance claim 1, col. 10, lines 19-31 "regulate first fill regulator...regulate second fill regulator", in each of the first and second stations.

The subject-matter of claim 1 of the present invention is thus clearly distinguished from the disclosure of Ebey by the presence of the steps relating to a) measurement of a parameter representative of the hardness of the tablet, and b) regulating the degree of compression on the basis of this measurement. Accordingly, it is submitted that independent claim 1 and its dependent claims 2-16 patentably distinguish over the prior art.

In addition, Applicants submit that new method claim 34 is also patentable over the prior art for the reasons discussed above.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

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Respectfully submitted,



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